



US005643596A

United States Patent [19]

Pruss et al.

[11] Patent Number: **5,643,596**
 [45] Date of Patent: **Jul. 1, 1997**

[54] **HEMOSTATIC PATCH**

[75] Inventors: **Thaddeus P. Pruss**, Baltimore, Md.;
James A. Will, Columbus, Wis.

[73] Assignee: **Clarion Pharmaceuticals, Inc.**,
 Madison, Wis.

[21] Appl. No.: **474,127**

[22] Filed: **Jun. 7, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 146,360, Nov. 3, 1993, abandoned.

[51] Int. Cl.⁶ **A61K 9/70**

[52] U.S. Cl. **424/426; 424/422; 424/423;**
424/443; 424/444; 424/484; 424/499; 514/2;
514/21; 514/557; 514/561

[58] Field of Search **424/426, 422,**
424/423, 443, 444, 484, 499; 514/2, 21,
557, 561

[56] **References Cited****U.S. PATENT DOCUMENTS**

2,610,625	9/1952	Sifferd et al.	128/156
3,157,524	11/1964	Artandi	106/122
3,731,683	5/1973	Zaffaroni	128/268
3,797,494	3/1974	Zaffaroni	128/268
3,854,480	12/1974	Zaffaroni	128/260
3,908,018	9/1975	Choay	424/319

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0 059 265	9/1982	European Pat. Off.
0090997	10/1983	European Pat. Off.
1960614	6/1976	Germany
292840 A5	8/1991	Germany
54-98091	8/1979	Japan
1099565	4/1989	Japan

(List continued on next page.)

OTHER PUBLICATIONS

"The Effectiveness of a Fibrinogen-Thrombin-Collagen-based Hemostatic . . .", Schelling et al., *Annals of Surgery*, vol. 205(4), Apr. 1987, pp. 432-435.

"Autologous Fibrin Tissue Adhesive Biodegradation and Systemic Effects", Abstracts, Harris et al., *Laryngoscope*, vol. 97(10), Oct. 1987, pp. 1141-1144.

"Application of Fibrinogen-Thrombin-Collagen-Based Hemostatic Agent . . .", Schelling et al., *T. Journal of Trauma*, vol. 28(4), Apr. 1988, pp. 472-475.

"Fibrin Glue: A Review of the Preparation, Efficacy, and Adverse . . .", Abstract, Thompson et al., *Drug Intell. Clin. Pharm.*, vol. 22(12), Dec. 1988, pp. 946-952.

"Pepsin Fibrinolysis of Artificial Clots . . . the Effect of pH and . . .", Abstract, *Surg. Endosc.*, vol. 3(3), 1988, pp. 148-151.

"Autologous Fibrin Glue in Full-Thickness Skin Grafting", Abstract, Chakravorty et al., *Ann. Plast. Surg.*, vol. 23(6), Dec. 1989, pp. 488-491.

(List continued on next page.)

Primary Examiner—Gollamudi S. Kishore
Attorney, Agent, or Firm—Millen, White, Zelano, & Brangan, P.C.

[57] **ABSTRACT**

A fibrogen-free substrate having as a hemostatic agent on a surface thereof a mixture of a clot-promoting amount of thrombin and an amount of epsilon aminocaproic acid (EACA) effective to accelerate the rate of blood clotting induced by the thrombin is useful as a hemostatic patch which is safe, inexpensive and which rapidly controls bleeding from a wound. A patch which rapidly stanches the flow of blood from a lesion on a parenchymal organ by pressing it against the surface of the organ for 3-5 minutes, is produced by applying thrombin, EACA and CaCl₂ to a rigid sheet of biodegradable foam, such as an absorbable gelatin sponge, and compressing the dry sheet to produce a flexible sheet which conforms to the contour of the organ without the necessity of pre-moistening. The problem associated with thrombin-fibrinogen glues of adhesion of the wounded surface of the organ to adjacent tissue is avoided by applying the hemostatic agent to only the wound-contacting face of the sheet.

17 Claims, 4 Drawing Sheets